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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,058	06/20/2003	Knut Elbers	1/1120/25/26-1-C1	2518

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EXAMINER

SALIMI, ALI REZA

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/600,058	Applicant(s) ELBERS ET AL.	
	Examiner A R. Salimi	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/772,316.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/20/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-13 are pending.

Raw Sequence Listing have been entered.

Submitted Information Disclosure Statement (I.D.S) is noted.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence(s) of the specification or in an application data sheet by identifying the prior application by application number (37 CFR 1.78(a)(2) and (a)(5)). If the prior application is a non-provisional application, the specific reference must also include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number. Please up-date the information, i.e. insert abandoned where appropriate.

Claim Rejections - 35 USC § 112

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite for recitation of “essentially”, this is a relative term subject to varied interpretations. The claim has been interpreted in light of the specification and since the specification does not set forth what “essentially” is intended to mean, the claim is considered vague and indefinite. Still further, the claim is vague and indefinite for recitation of “less virulent”, this is a relative term, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill

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in the art would not be reasonably apprised of the scope of the invention. This affects the dependent claims.

In addition, claims 5-7 are vague and indefinite and rather confusing, since the VR-2332 is a deposited virus and not a deposited sequence, hence, no reasonable search or comparison can be made if the specific sequence is not recited. This affects the dependent claims.

Claim Rejections - 35 USC § 112

Claims 1-4, 13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a live attenuated virus capable of treatment, does not reasonably provide enablement for a method of prophylaxis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. The specification does not set forth an adequate teaching of prophylaxis utilizing broad attenuated PRRS viruses now being claimed. Applicants own specification admits that present attenuated pharmaceutical compositions do not prevent re-infection (see page 3, middle paragraph). In addition, there are no examples or any data present in the specification to support for prophylaxis. Applicants have general statements regarding the prophylaxis method to PRRS. However with regard to an unpredictable field, this does not constitute an adequate disclosure. See *Fiers v. Revel* (25USPQ2d 1601 at 1606; and also decision by the Federal Circuit with regard to the enablement issues see *Genentech Inc. v. Novo Nordisk A/S*, 42 USPQ2d 1001-1007). For example, the CAFC stated that "It is the specification, not the knowledge of one skilled in the art that must

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supply the novel aspects of an invention in order to constitute enablement.” (See page 1005 of the decision). In the instant case the specification does not teach or provide any guidance for development of a vaccine to induce prophylaxis for PRRS. This means that the disclosure must adequately guide the art worker to determine, without undue experimentation. The applicant cannot rely on the knowledge of those skilled in the art to enable the claims without providing adequate teaching. Therefore, considering large quantity of experimentation needed, the unpredictability of the field, the state of the art, and breadth of the claims, it is concluded that undue experimentation would be required to enable the intended claim. Many of these factors have been summarized *In re Wands*, 858 F.2d 731, USPQ2d 1400 (Fed. Cir. 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-4, 12, 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Chladek et al (U.S Patent no. 6,042,830).

The claims are directed to an attenuated virus of VR-2332. The above cited patent taught an attenuated VR-2332 virus passaged at least 70 times, method of immunizing and method of making attenuated VR-2332. The claims of the above cited

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patent meets the limitations of the claimed invention (see claims 1-16). The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products. Hence, the disclosure and the claims of the above cited patent anticipates the claimed invention. Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claims 1-4, 12, 13 are rejected under 35 U.S.C. 102(e) as being anticipated by Collins et al (U.S Patent no. 6,110,468).

The above cited patent taught an attenuated VR-2332 virus, suitable for use in prevention of PRRS (see claims 1-19). The product disclosed in the above cited patent appears to be identical or so similar that is indistinguishable from the product claimed by the applicants. Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Paul et al (U.S Patent no. 6,251,397).

The composition of the ORFs including ORF2 of PRRSV especially the limitations of percent identity (see claim 3) anticipates the claimed invention (see claims

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1-3). Applicants are reminded that the Patent Office does not have facilities to perform physical comparisons between the claimed product and similar prior art products.

Moreover, if the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. R. Salimi whose telephone number is (571) 272-0909. The examiner can normally be reached on Monday-Friday from 9:00 Am to 6:00 Pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (571) 272-0902. The Official fax number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. R. Salimi

8/10/2005

ALI R. SALIMI
PRIMARY EXAMINER